MAZIE SLATER KATZ & FREEMAN, LLC

103 Eisenhower Parkway, Suite 207, Roseland, NJ 07068 Phone: (973) 228-9898 - Fax: (973) 228-0303 www.mazieslater.com

David A. Mazie* Adam M. Slater*° Eric D. Katz*° David M. Freeman Beth G. Baldinger Matthew R. Mendelsohn° David M. Estes

Certified by the Supreme Court of New Jersey as a Civil Trial Attorney °Member of N.J. & N.Y. Bars Karen G. Kelsen° Cheryll A. Calderon Adam M. Epstein° Cory J. Rothbort° Michael R. Griffith° Christopher J. Geddis Alexander Q. Reynoso Samuel G. Wildman Julia S. Slater°

January 12, 2021

VIA ECF

Honorable Joel Schneider
United States Magistrate Judge
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, New Jersey 08101

Re: IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION Civil No. 19-2875 (RBK/JS)

Dear Judge Schneider:

Please accept this letter on behalf of the Plaintiffs in advance of the upcoming January 13, 2021 status conference.

1. Status of Scheduling Depositions

The parties continue to meet and confer regarding the scheduling of the many defense corporate witnesses who are ordered to be deposed by the end of March 2021. Before getting into a discussion of the details, it is critical to remember that this litigation has been ongoing for two years, the Defendants were given more than one year to produce documents, and Plaintiffs are now being asked to conduct all manufacturer depositions – while defending a host of depositions of

plaintiffs – in only two months. This is a highly complex task, even without reference to the logistical problems introduced by the pandemic.

As set forth in more detail below, agreement has been reached on some witnesses, but the scheduling remains unresolved in many instances, across all Defendants. Plaintiffs are committed to continuing discussions in the hope that more depositions can be agreed to, as it is obviously preferable for the parties to reach agreement.

Among the difficulties faced in general, a large number of depositions are still being offered only in March 2021 despite the Court's recent Order to the contrary. In addition, certain Defendants have indicated that they will only agree to very limited time for the depositions, for example asking Plaintiffs why important groups of 30(b)(6) topics cannot be addressed in a total of three hours. Plaintiffs have spent a great deal of time drilling down on each witness in order to propose reasonable lengths for each deposition. First, fact witnesses with no 30(b)(6) topics are not difficult – Plaintiffs have agreed to one day per the protocol for a pure fact witness. For 30(b)(6) witnesses, all of whom are being deposed as fact witnesses as well, Plaintiffs have calculated the necessary length based on a presumption of one day for the fact witness deposition, following the time needed to address the 30(b)(6) topics., If less time is needed, the deposition will not be extended to fill the time – wasting Plaintiffs time and money for no good reason. Plaintiffs analyzed each witness individually since none have the same number or collection of topics, and it is important to take into account the scope and complexity of information to be addressed with

_

The lengths discussed are without reference to the 75% additional time for witnesses deposed with translators since that should not be a factor in setting the lengths of the depositions. That additional time is to be added where necessary to equalize the ability to take the deposition on a reasonable basis due to the presumed delay from using translators, over Zoom.

Honorable Joel Schneider, U.S.M.J. January 12, 2021

Page 3

the witnesses. The schedule and lengths proposed by Plaintiffs is a product of this extensive analysis. Plaintiffs have also advised the defense that to the extent more time is needed for the 30(b)(6) topics, the default would be to eat into the day ascribed to the fact witness part of the deposition, and effort made to complete the deposition within the assigned length.

In response, some Defendants have engaged only sporadically, and the discussions have not advanced adequately. In some instances, Defendants have been unwilling to even discuss the deposition lengths witness by witness, instead positing facially inadequate blocks of total time that they propose Plaintiffs should allocate among the depositions – as if trying a case on a time clock - which is completely unreasonable, as it is impossible for Plaintiffs to know what the witnesses will say or how to reliably allocate time – even assuming the total time were adequate. In fact, Plaintiffs would be forced to artificially shorten depositions all along the way in order to ensure that they would not run out of time at the end of the process. If any Defendant presses such a proposal, Plaintiffs object outright.

The following discussion of the status of negotiations is Plaintiffs' best effort to submit a snapshot of the status of the discussions. Plaintiffs are hopeful that by the time of the conference significant additional progress will have been made and agreements will have been reached across the board, or at least with few exceptions.

2. ZHP Deposition Scheduling and Lengths

On January 6, 2021, Plaintiffs proposed lengths for the ZHP Defendants' 30(b)(6) depositions based on the number and complexity of each deponent's topics. (Ex. A hereto). Two days later, the ZHP Defendants rejected Plaintiffs' proposal entirely and offered to give Plaintiffs a total of fifteen hours to depose ZHP's 30(b)(6) witnesses on all topics and five hours for its

subsidiary's witnesses on all topics they are testifying on. In other words, the equivalent of a two-day deposition to address all 30(b)(6) topics with ZHP, and less than one day with ZHP's subsidiaries. *Id.* In light of the volume and complexity of the documents and subject matter, this is obviously unreasonable and not even a helpful point of discussion. The Parties met and conferred on January 11, 20201. Although the Parties hope to reach a resolution to this issue before the Status Conference, ZHP has yet to change its position as of the filing of this letter.

In order to give some perspective before discussing individual witnesses, Plaintiffs note that the documents in this litigation number in the millions, are voluminous, and complex. For example, ZHP wrote four deviation investigation reports on the nitrosamine contamination of their valsartan. The first is 109 pages, the second 167, the third 303, and the fourth 25. After completing these investigations, in December 2018, ZHP sent the FDA 339 pages of documents in an attempt to explain the contamination and get the FDA to lift its import ban of ZHP's valsartan. Although ZHP has continued to try to convince the FDA otherwise ever since, the FDA has not accepted ZHP's explanation of the contamination and continues to ban its valsartan from import into the United States. The documents are similar for the other manufacturers. For example, [insert other similar reports].

The first 30(b)(6) witness, **Lijie Wang**, is the Vice President of Regulatory Affairs at Prinston, where she has worked there since 2017. She will address **seven topics** (**four topics on behalf of Prinston and three on behalf of Huahai US)** concerning process development and communications with regulatory agencies. This includes subjects such as the health risks due to the contamination, and the regulatory submissions regarding manufacturing changes and

ultimately the contamination itself. Plaintiffs have proposed **a total of a day and a half** to depose this witness as both a 30(b)(6) and fact witness.

Hai Wang has been the President of Solco since 2017. He worked at Prinston from 2016 to 2017, and Huahai US from 2005 to 2016. He will address **nineteen topics (seven topics on behalf of ZHP, two on behalf of Prinston, and ten on behalf of Solco)** concerning ZHP's communications with API and finished dose customers and downstream customers, product tracing, testing of valsartan API. This includes subjects such as communications with customers regarding the quality, purity, and contamination of ZHP's finished dose valsartan; the tracing of ZHP's finished dose valsartan downstream; the sales and pricing data for finished dose valsartan; and the nitrosamine levels found in ZHP's valsartan API and finished dose, both in terms of the concentration per pill, and across all of the lots/batches. Plaintiffs have proposed **a total of two and a half days** to depose this witness as both a 30(b)(6) and fact witness.

Minli Zhang is currently the Director of Finished Dose Formation Quality at ZHP, where she has worked since 2001. She will address **twenty topics on behalf of ZHP** concerning the testing of Valsartan API, quality assurance and quality control activities, ZHP's communications with API and finished dose customers and downstream customers, and compliance with cGMPs. This includes subjects such as the extensive chromatogram and mass spectrometry testing of ZHP's finished dose valsartan; the standard operating procedures intended to prevent, detect, or act in response to any impurity or contamination; application of cGMPs intended to prevent, detect, or act in response to any impurity or contamination; ZHP's statements to customers regarding the contents, purity, and contamination of its valsartan API and finished dose; ZHP's recall of valsartan finished dose; and ZHP's compliance or lack thereof with cGMPs intended to prevent,

detect, or act in response to any impurity or contamination. Plaintiffs have proposed a total of three days to depose this witness as both a 30(b)(6) and fact witness.

Qiangming Li is ZHP's Senior Director of Analysis, and he has worked for ZHP since 2013. He will address **nine topics on behalf of ZHP** concerning the testing of valsartan API. This includes subjects such as the extensive chromatogram and mass spectrometry testing of ZHP's valsartan API and the extent of the nitrosamine contamination it ZHP's valsartan API, both in terms of the concentration per pill, and across all of the lots/batches. Testing is one of the central issues of this case, and Mr. Li was involved in preparing the longest deviation investigation report mentioned above. Plaintiffs have proposed **a total of two and a half days** to depose this witness as both a 30(b)(6) and fact witness.

Hong (Eric) Gu has been the President of Shanghai Syncores since 2014. He will address two topics on behalf of ZHP concerning the process development of its valsartan. As this Court already knows, Shanghai Syncores developed ZHP's lab scale process for its contaminated valsartan and even told ZHP that it needed to implement the process at a pilot scale in order to optimize the purification process and solvent system before using it to manufacture valsartan at a larger scale. Mr. Gu is consequently a key witness in this case. Plaintiffs have proposed a total of two days to depose this witness as both a 30(b)(6) and fact witness.

Jucai Ge is the Director of API Quality Assurance at ZHP, where he has worked since 2000. She will address 12 topics on behalf of ZHP concerning the testing of valsartan API, quality assurance and quality control activities, and compliance with cGMPs. This includes subjects such as the root cause investigation for the nitrosamine contamination; ZHP's standard operating procedure intended to prevent, detect, or act in response to any impurity or

contamination; the application of cGMPs intended to prevent, detect, or act in response to any impurity or contamination; and ZHP's recall of valsartan API. These topics are the heart of this case. Plaintiffs have proposed **a total of three days** to depose this witness as both a 30(b)(6) and fact witness.

Lihong (Linda) Lin is the Director of Regulatory Affairs at ZHP, where she has worked since 1997. She will address **four topics on behalf of ZHP** concerning communications with regulatory agencies. This includes subjects such communications with any regulatory agency with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API and finished dose; the disclosure of the nitrosamine contamination to any regulatory agency; and ZHP's filings with regulatory authorities, including the FDA, regarding manufacturing process changes for ZHP's Valsartan API Drug Master Filings. Plaintiffs have proposed **a total of** two **days** to depose this witness as both a 30(b)(6) and fact witness.

Min Li is the Vice president of Analysis and Testing at ZHP, where she has worked since 2014. He will address **four topics on behalf of ZHP** concerning testing of valsartan API and process development. These are two of the most important topics of this litigations. This includes subject such as the cause of the nitrosamine contamination, the root cause investigation of the nitrosamine contamination; chromatogram and mass spectrometry results for all valsartan API and finished dose; and ZHP's evaluation and knowledge of the health risks of nitrosamines. Plaintiffs have proposed **a total of two and a half days** to depose this witness as both a 30(b)(6) and fact witness.

Jie (Jay) Wang is the Vice President of Business Development at ZHP, where he has worked since 2013. He will address **eight topics on behalf of ZHP** concerning ZHP's communications with API and finished dose customers and downstream customers and product tracing. This includes subject such as ZHP's communications with Novartis regarding the discovery of the nitrosamine contamination; ZHP's communications with valsartan API customers; ZHP's valsartan API pricing; ZHP's profits from valsartan API; and the quantity/unites of ZHP's valsartan API sold in the United States. Plaintiffs have proposed **a total of two days** to depose this witness as both a 30(b)(6) and fact witness.

Peng Dong is the Director of Technology, Department I at ZHP, where he has worked since 2006. He will address **five topics on behalf of ZHP** concerning the testing of valsartan API and process development. This includes subjects such as ZHP's evaluation of the potential risks to the purity or contents of ZHP's valsartan API posed or caused by solvents used during the manufacturing process; the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API; and any evaluation conducted by or on behalf of ZHP with regard to health or safety issues arising from the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API. Importantly, Mr. Dong was also involved in preparing all four of the deviation investigation reports mentioned above. Plaintiffs have proposed **a total of two and a half days** to depose this witness as both a 30(b)(6) and fact witness.

For the convenience of the Court, Plaintiffs have attached a calendar of their proposed deposition schedule followed by a short description of each witness and a list of their assigned 30(b)(6) topics, if applicable. (Ex. B hereto). In the event that agreement cannot be reached

between the parties, Plaintiffs respectfully request the Court order the schedule as reflected in that calendar.

3. Hetero Deposition Scheduling and Lengths

On January 4, 2021, Plaintiffs proposed lengths for the Hetero Defendants' 30(b)(6) depositions based on the number and complexity of each deponent's topics. In short, Plaintiffs requested three days for Venkataramana Madireddy, who was designated to testify on **15 topics** (the most of any Hetero witness), and two days for the remaining 30(b)(6) witnesses. Plaintiffs had also previously proposed the depositions of several fact witnesses.

Plaintiffs' counsel and Hetero's counsel have unsuccessfully exchanged proposals in an effort to reach an agreement as to the lengths of the depositions. Hetero's latest proposal offers just two days to depose Venkataramana Madireddy while leaving open an option to discuss the need for an additional half day. Hetero also proposed to limit the remaining 30(b)(6) witness depositions to one day. Plaintiffs cannot accept Hetero's proposal. This is particularly problematic with respect to Panchakshari Nanyappa Gowda, who is designated to testify on nine topics, and Dr. B.V. Ramireddy, both of whom will be testifying on testing topics.

Complicating matters further, Hetero limited the dates of Hetero's 30(b)(6) witnesses to the first two weeks in March (from March 1 through March 12). Plaintiffs requested additional dates in February, to which Hetero's counsel offered one additional week (February 22 through February 26) to schedule depositions. Moreover, Hetero still has not stated one way or another whether it would agree to the proposed fact witness depositions, which was first proposed by Plaintiffs on December 23, 2020.

Plaintiffs' proposed scheduled is attached as Exhibit C. The chart contains a description of the witness, the assigned 30(b)(6) topics, minimum deposition length, and proposed dates.

4. Mylan Deposition Scheduling and Lengths

Plaintiffs' latest proposal to Mylan in an effort to compromise is set forth herein. Because Mylan has designated, somewhat dubiously, a single witness (Mr. Derek Glover) to cover twenty-eight (28) of the total fifty-four (54) 30(b)(6) topics across a range of topical areas, Plaintiffs have proposed two full days of 30(b)(6) deposition time with Mr. Glover. Plaintiffs have only requested half days each (3.5 hours each) of 30(b)(6) time for Ms. Katie Reed and Dr. Daniel Snider. Plaintiffs also request full days of 30(b)(6) time with Messrs. Talton and Molnar. These are more than reasonable requests proffered by Plaintiffs to Mylan at an effort to reach a compromise without requiring the Court's intervention.

As for individual fact witnesses including the individual time spent with the above 30(b)(6) designees, the lengths are assumed to be 1 full day each (consisting of 7 hours of on-the-record time), although Plaintiffs can make assurances that no one's time will be wasted. Mylan has agreed to produce four U.S.-based witnesses (Owens, Bird, Malki, Kupec), and the parties have not agreed on a number of India-based witnesses. It is, of course, India and specifically Mylan's Unit 8 API manufacturing facility in India where the majority of the relevant events are alleged to have occurred relating to the contamination of Mylan's VCDs. Plaintiffs are entitled to depose a number of these key individuals because they contain relevant factual knowledge. In an effort at compromise, Plaintiffs have removed a majority of the names from their foreign deponents' list, and most recently communicated to Mylan's counsel that Plaintiffs would agree to deposing just four (4) high-level India-based witnesses (Gomas, Basade, Abbenini, and Kolla), all of whom

easily meet the "managing agent" test set forth in *In re Takata Airbag Prods. Liab. Litig.*, MDL No. 2599, 2017 WL 8812735, at *2-3 (S.D. Fla. July 9, 2017) (Ex. D hereto), to qualify as party witnesses under Rule 30(b)(1).

A calendar setting forth Plaintiffs' proposed deposition dates is attached as Exhibit E.

5. Teva Deposition Scheduling and Lengths

Teva has not agreed to scheduling and lengths of depositions. In fact, Teva has neither (i) offered any deposition dates for its Rule 30(b)(6) designees prior to March, nor (ii) even agreed to produce any individual deponent requested by Plaintiffs, let alone engaged in discussion about the lengths of depositions.

On December 22, 2020, Plaintiffs informed Teva of the individual deponents they sought to depose, in addition to the seven Rule 30(b)(6) designees previously suggested by Teva. Teva also exclusively provided depositions dates in March for its Rule 30(b)(6) designees. Teva was not available to meet and confer about any depositions until January 4, 2021. At that time, Plaintiffs requested that Teva offer dates for its Rule 30(b)(6) designees in January and February (and not just March), and to provide dates for the individual deponents. Teva claimed it would not provide earlier dates because its TAR-related re-review and production will not be complete until February 15, 2021. Plaintiffs nonetheless suggested that *some* deponents (designees or individual deponents) could be deposed prior to March, such as those being designated on very discrete topics such as sales and pricing data, or those for whom custodial productions are complete and will not be impacted by the TAR-related re-review.

Two days later, the Court informed all parties:

Between now and January 13th you work with the defendants to move these depositions up. It's unacceptable to the Court that 90 percent of the depositions start in March. And if the defendants don't agree to produce witnesses earlier than that, I'll order them to be produced on January 13.

So, roll up your sleeves, all the parties; be reasonable and professional. It's unacceptable that we're pushing all of these depositions back to the March and April time period. It's a short time period and there's no reason whatsoever to delay the start of the depositions and leave a gap between mid-January and March.

The Court is completely unsympathetic to the argument that these document productions haven't been done yet. They should have been done already.

See 1/5/21 Tr. at 10. Despite the Court's instruction that the parties should "roll up [their] sleeves," Plaintiffs never heard back from Teva after the January 5 hearing. Given Teva's failure to heed the Court's admonition last week and engage in further discussions with Plaintiffs, Plaintiffs' proposed scheduled is attached as Exhibit N. The chart contains a description of the witness, the assigned 30(b)(6) topics, minimum deposition length, and proposed dates. The dates listed are *not* the dates Plaintiffs want or agree to. Instead, Plaintiffs have tentatively listed every requested Teva deponent (be they designee or individual) for March, because that is the only month Teva has even discussed at this point. Clearly, this calendar, with one Teva deponent scheduled every business day in March, is facially unworkable, and requires Teva to produce several witnesses prior to March.

6. Torrent Deposition Scheduling and Lengths

Torrent has provided dates for 30(b)(6) but has not provided any dates for witnesses being deposed in their individual capacity only, except for a single day for such a witness. The Parties have another meet and confer scheduled for today.

7. Aurobindo Deposition Scheduling and Lengths

Aurobindo has failed to provide a complete slate of acceptable dates for their witnesses. Plaintiffs have proposed a schedule attached as Exhibit Q.

8. Chinese State Secret Laws

Under Federal Rule of Civil Procedure 26(b)(5) and the Court's ESI Order (ECF 127), the party asserting the privilege must provide the opposing party and ultimately the Court with, among other things, "a specific explanation of why each document is privileged or immune from discovery," which "must include a comprehensive presentation of all factual grounds and legal analyses in a non-conclusory fashion." Pippenger v. Gruppe, 883 F. Supp. 1201, 1212 (S.D. Ind. 1994); see also Chao v. Koresko, Nos. 04-3614, 05-1440, 05-1946, 05-2673, 2005 WL 2521886, at *4 (3d Cir. Oct. 12, 2005) (Ex. F hereto); Wachtel v. Health Net, Inc., 239 F.R.D. 81, 106 (D.N.J. 2006). Judge Kugler has previously made clear that "[a] proper privilege log must include, for each withheld document, the date of the document, the name of its author, the name of its recipient, the names of all people given copies of the document, the subject of the document, and the privilege or privileges asserted." Torres v. Kuzniasz, 936 F. Supp. 1201, 1208 (D.N.J. 1996) (citing Wei v. Bodner, 127 F.R.D. 91, 96 (D.N.J.1989)). Moreover, documents containing non-privileged information should be produced with the limited privileged information redacted. See, e.g., McKee v. PetSmart, Inc., 71 F. Supp. 3d 439, 443 (D. Del. 2014) (holding that "to the extent that the PowerPoint presentation may constitute a combination of facts, which are discoverable, and legal conclusions regarding those facts, which are not discoverable, defendant should produce a redacted version of the PowerPoint presentation to plaintiffs."); Benefitvision Inc. v. Gentiva Health Servs., Inc., No. CV 09-473, 2011 WL 3796324, at *2 (E.D.N.Y. May 23,

2011) (holding that "[i]f there are e-mail chains in which Defendants claim privilege over only parts of the e-mail chain, those allegedly privileged e-mails must be redacted and all non-privileged portions must be produced.") (Ex. G hereto); *S.E.C., Inc v. Wyly*, No. 10 Civ. 5760, 2011 WL 3851129, at *5 (S.D.N.Y. June 17, 2011) (same) (Ex. H hereto).

When a party has failed to comply with this rule, courts have ordered the party to amend their privilege logs "to allow either plaintiffs or [the c]ourt to evaluate what, if any, claims of privilege [the defendant] may have." *Wultz v. Bank of China Ltd.*, 979 F. Supp. 2d 479, 497 (S.D.N.Y. 2013). After having this opportunity to amend and failing to comply with the court's order, courts have held that the party "will have waived any claims of privilege over those documents." *Id.*; *see also Chao*, 2005 WL 2521886, at *4. The "large volume" and "foreign" or "challenging" nature of the relevant discovery will not excuse compliance with these requirements. *Id.*

Moreover, the "party relying on foreign law has the burden of showing that such law bars production." *Schindler Elevator Corp. v. Otis Elevator Co.*, 657 F. Supp. 2d 525, 532 (D.N.J. 2009). Some Chinese laws prohibit the disclosure of "state secrets . . . without the government's permission." *Autodesk, Inc. v. ZWCAD Software Co. Ltd.*, No. 5:14–cv–01409–EJD, 2015 WL 1928184, at *4 (N.D. Cal. Mar. 27, 2015) (Exhibit I hereto). For example:

Article 2 of China's State Secrets Law defines state secrets as "matters that have a vital bearing on state security and national interests and, as specified by legal procedure, are entrusted to a limited number of people for a given period of time."

Id. "Article 8 expands this definition to include, among other materials, matters that involve 'national economic and social development' and 'science and technology." *Id.* In Defendants'

November 23, 2020 agenda letter (ECF 637), ZHP cited a single case in support of enforcing Chine state secret laws, and that case involved at least seven different Chinese banking laws allegedly baring the discovery. *See Tiffany (NJ) LLC v. Qi* Andrew, 275 F.R.D. 143, 150 (S.D.N.Y. 2011). Thus, Chinese "laws have broad sweep and can preclude disclosure of a host of nebulously defined categories of information." *Munoz v. China Expert Tech., Inc.*, No. No. 07 Civ. 10531, 2011 WL 5346323, at *1 (S.D.N.Y. Nov. 7, 2001) (citing *Richmark Corp. v. Timber Falling Consultants*, 959 F.2d 1468, 1477 (9th Cir.1992)) (Exhibit J hereto).

Given the vague applicability of the state secret laws and the withholding party's burden to show that the laws apply, Chinese state secret laws "are viewed with some skepticism in U.S. courts." *Munoz*, 2011 WL 5346323, at *1; *see also Richmark*, 959 F.2d at 1477 (rejecting the withholding party's invocation of Chinese state secret law); *Meggit (Orange Cty.), Inc. v. Nie Yongzhon*, No. SACV 13–0239–DOC, 2015 WL 1809354, *11 (C.D. Cal. Apr. 21, 2015) (same) (Exhibit K hereto); *Autodesk*, 2015 WL 1928184, at *4 (same); *Masimo Corp. v. Mindray DS USA, Inc.*, No.: SACV 12-02206, 2014 WL 12589321 (C.D. Cal. May 28, 2014) (same) (Exhibit L hereto). ²

In fact, "[t]he Supreme Court has stated that '[i]t is well settled that [foreign "blocking"] statutes do not deprive an American court of the power to order a party subject to its jurisdiction to produce evidence even though the act of production may violate that statute."

Plaintiffs note that none of these cases involved a "privilege log" for Chinese state secrets. Instead, the withholding party moved for a protective order, which the court ultimately denied. ZHP should have done the same here. Instead, ZHP waited over a month after its production was due to inform Plaintiffs and the Court that it had withheld hundreds of documents and redacted others, and when it did so, it failed to even provide a reasonable basis.

Munoz, 2011 WL 5346323, at *1 (quoting Societe Nationale Industrielle Aerospatiale v. United States Dist. Ct., S.D. Iowa, 482 U.S. 522, 544 n. 29 (2011)). In Societe Nationale, the U.S. Supreme Court endorsed the following factors "in deciding whether or not foreign statutes excuse noncompliance with discovery orders:"

- (1) "[T]he importance to the investigation or litigation of the documents or other information requested,"
- (2) "[T]he degree of specificity of the request,"
- (3) "[W]hether the information originated in the United States,"
- (4) "[T]he availability of alternative means of securing the information," and
- (5) [T]he extent to which noncompliance with the request would undermine important interests of the United States, or compliance with the request would undermine important interests of the state where the information is located."

Richmark, 959 F.2d at 1475 (quoting Restatement (Third) of Foreign Relations Law § 442(1)(c)) (citing Societe Nationale, 482 U.S. at 2556 n.28). However, these factors are "not exhaustive." *Id.* Courts have also considered "the extent and the nature of the hardship that inconsistent enforcement would impose upon the person, ... [and] the extent to which enforcement by action of either state can reasonably be expected to achieve compliance with the rule prescribed by that state." *Id.* (quoting *United States v. Vetco, Inc.*, 691 F.2d 1281, 1288 (9th Cir.), *cert. denied*, 454 U.S. 1098 (1981)). After weighing these factors, the Ninth Circuit has even affirmed the disclosure of information after the Chinese Secrecy Bureau ordered a party "not to disclose or provide the information and documents requested by the United States District Court for the District of

Oregon," and warned that the party "shall bear any or all legal consequences should you not comply with this order." *Id.* at 1476, 1478-79.

In *Autodesk*, the court held that:

ZWSoft also does not show that there is a genuine risk that production of its source code and related documents under the current protective order could subject ZWSoft to liability under Chinese state secret and privacy laws. ZWSoft is correct that China has imposed "severe" penalties upon people who have violated its state secrecy or privacy laws. But once again, ZWSoft's generalized, unsubstantiated claims about Chinese law do not establish that there is a "present danger that application of the PRC blocking statutes" could subject ZWSoft to liability if it produces its source code and related documents in the United States.

2015 WL 1928184, at *8 (footnotes removed); *see also Masimi*, 2014 WL 12589321, at *3 (noting that the withholding party "has presented no evidence regarding the extent to which the Chinese government enforces its secrecy laws, or the likelihood that any criminal as opposed to only civil or administrative penalties will be issued, making that factor similarly less persuasive in its favor").

Against this backdrop, ZHP's state secret log is not helpful, and does not allow Plaintiffs or this Court to assess its invocation of Chinese State secret laws for numerous reasons. First, the log does not state the specific Chinese state secret law barring production. ZHP has the burden of proving Chinese law prohibits the discovery, so it should specifically state which law bars the production and provide the text of that law to plaintiffs and ultimately the Court for their review. Second, the log contains conclusory descriptions, such as "Confidential internal documents of PRC government authorities," that do not allow Plaintiffs or this Court to assess the propriety of the invoke privileged. Instead, they essentially restate the fact that ZHP believes the information is a Chinese state secret. Third, the log does not include the titles of the individuals named and omits

the names and titles of the Chinese government authorities related to the documents. All this information is necessary for Plaintiffs and this Court to assess ZHP's invocation of Chinese state secret law. The Court should order ZHP to amend its Chinese state secret law accordingly.

On January 1, 2021, Plaintiffs emailed ZHP regarding the above deficiencies with its Chinese state secret log, and ZHP replied that it had thirty days to provide a complaint privilege log. (Ex. M hereto). Plaintiffs asked to meet and confer further on this issue, but they never heard back from ZHP. *Id.* To the extent ZHP maintains its position that it has thirty days to provide an adequate privilege log, this Court should note that the ESI order's reference to thirty days only applies to requests for "further information" regarding specific documents that goes beyond the requirements of an adequate privilege log, as explained above. (See ECF 127, p. 18). ZHP was required to provide that log last year. It cannot perpetually give itself a thirty-day extension by repeatedly failing to comply with the ESI order and Federal Rules of Civil Procedure. With the depositions imminent, things need to move much faster. The Court should consequently order ZHP to serve an adequate Chinese state secret log this week.

9. Defendants' Withholding of Non-Party Documents Received via Plaintiff-Executed Authorizations (Cost Sharing)

Plaintiffs twice attempted to meet and confer with Defendants about this issue following the January 5 CMC (via emails sent after the CMC on January 5, and another more detailed email sent on January 7), but Defendants never responded. Plaintiffs' position is as follows.

As to all personal injury and consumer class Plaintiffs, Defendants should produce to Plaintiffs without charge all records that Defendants request and receive via authorizations. These records requests are essentially third-party subpoenas where Defendants have chosen to use a

vendor for collection and storage. As is the case with any documents obtained through third-party subpoenas for which a party uses a vendor to obtain documents but must share the results of such subpoenas with all other parties without cost sharing, there is no basis for cost sharing for the vendor used to obtain these documents. See, e.g., Oppenheimer Fund, Inc. v. Sanders, 437 U.S. 340, 358 (1978) (presumption is party bears their own discovery expenses); Edwards v. City of Bossier City, No. 15-1822, 2016 WL 3951216, at *5 (W.D. La. July 20, 2016) ("defendants resorted to self-help via Rule 45. While the Rules ostensibly authorize this course of action, defendants have not identified any source to support their claim for reimbursement of the attendant costs, either under rule 45, or as a discovery sanction where, as here, plaintiff made at least some effort to identify medical providers and to provide defendants with copies of those medical records. Accordingly, the court will not order reimbursement") (Ex. O hereto). Defendants, in failing to even meet and confer with Plaintiffs, have failed to carry their burden of proof. See, e.g., Adams Pointe I, L.P. v. True-Flex Metal Hose Corp., No. 2:16-cv-00750, 2017 WL 11552833, at *2 (W.D. Pa. July 14, 2017) ("The party seeking cost-sharing for discovery bears the burden of proof.") (Ex. P hereto).

Plaintiffs already obtain their own sets of records in support of their claims and have to produce them to Defendants, free of charge. If Defendants intend on ordering copies of records for their own benefit, Plaintiffs' counsel should not bear the burden of sharing these costs. Further, just as Plaintiffs are required to share copies of any records they obtain with Defendants, the same should be true on the other side. At a minimum, if Defendants expect Plaintiffs to pay some of the costs of Defendants' obtaining records, then Defendants should pay some of the costs of Plaintiffs' obtaining records (records which Plaintiffs have been producing free of charge to date).

Further, as to consumer class Plaintiffs (i.e., individual named plaintiffs in the economic loss and medical monitoring actions), besides the above there additionally is no basis to shift the cost of Defendants' records collection efforts to Plaintiffs. These Plaintiffs do not seek damages for personal injury; thus, the records Defendants are collecting – including, e.g., x-rays, MRIs, etc. – have no bearing on Plaintiffs' claims.

In 2019, Defendants argued the only reason they needed these Plaintiffs' records was to confirm whether these Plaintiffs took VCDs, and whether they took other blood pressure medications. *See generally* 9/25/19 Tr. at 31-37. At that time, the Court posited that such records – relating to blood pressure medications – were the only ones Defendants needed; and Defendants agreed:

THE COURT: The document request says "for each healthcare provider identified in this fact sheet," so there's a question that relates to what providers they have to identify, what question is that. For example, if they went to see an orthopedist for a broken leg, you don't need that, right?

[DEFENSE COUNSEL] UNIDENTIFIED SPEAKER: I would tend to agree with that. I think at least -- at least for the fact sheet -- whether depositions lead elsewhere, but I think at least for the fact sheet what we're talking about is medical records relating to the conditions for which the patient was prescribed Valsartan or a Valsartan-containing medication.

19/25/19 Tr. at 33-34.

Consistent with this colloquy, the court-approved PFS for economic loss plaintiffs *only* requires plaintiffs to identify and provide authorizations for healthcare providers that prescribed valsartan or other treatment for high blood pressure:

VI. DOCUMENT DEMANDS

- A. <u>AUTHORIZATIONS</u> [To be served within twenty (20) days after service of the Plaintiff Fact Sheet ("PFS")]
- 1. Health Care Authorizations For each health care provider identified in Section IV of this Fact Sheet who prescribed or provided you medication for treatment of hypertension, including but not limited to Valsartan, Amlodipine/Valsartan, Valsartan/Hydrochlorothiazide (HCTZ), and/or Amlodipine/Valsartan/Hydrochlorothiazide (HCTZ), please provide a completed and signed (but undated) Health Care Authorization in the form attached as Exhibit "A."
- 2. Insurance Records Authorization For each insurance company identified in Section III of this Fact Sheet, please provide a completed and signed (but undated) Authorization for Release of Insurance Records in the form attached as Exhibit "B."
- B. <u>OTHER RELEVANT DOCUMENTS DEMANDS</u>

Requests for any non-privileged documents in your possession or the possession of your

Defendants, however, have been demanding authorizations for every single healthcare provider that appears in each plaintiff's records, be those providers podiatrists, eye doctors, or minute-clinics that treated a sprained ankle or common cold. To this point, Plaintiffs have been providing such authorizations in good faith, to avoid burdening the Court. But Plaintiffs' cooperation should not be punished by then forcing them to pay for third-party records that were never requested by Defendants or authorized by the Court in 2019 when the PFSs were finalized. All records should be produced by Defendants, free of charge, just like any other documents a party obtains from a non-party. *See, e.g., Edwards*, 2016 WL 3951216, at *5. Please let us know when we can discuss.

10. Wholesaler Defendant Objection to Production of T3 Data

Plaintiffs and Wholesaler Defendants currently are negotiating a proposed stipulation that may obviate the need for the Court's intervention concerning this issue.

Case 1:19-md-02875-RMB-SAK Document 731 Filed 01/12/21 Page 22 of 22 PageID:

Honorable Joel Schneider, U.S.M.J. January 12, 2021

Page 22

11. Plaintiffs' Draft Written Discovery and Deposition Notices to Retail Pharmacy and

Wholesaler Defendants

Plaintiffs had a preliminary meet and confer with Retail Pharmacy and Wholesaler

Defendants about Plaintiffs' draft written discovery and deposition notices on December 30.

Plaintiffs are conferring again with Retail Pharmacy Defendants later today (January 12, 2021),

and are waiting to hear back from Wholesaler Defendants about a follow-up meet and confer. It

Revised CMO No. 22 has now set an August 2, 2021 deadline for the completion of this and other

discovery directed to Retail Pharmacy and Wholesaler Defendants. Notwithstanding this, it is

Plaintiffs' expectation that the parties should continue to meet and confer so that Plaintiffs'

additional discovery requests and deposition notices can be finalized, and any disputes relating

thereto resolved by the Court, prior to the April 1, 2021 deadline to complete the first phase of fact

discovery. Plaintiffs wish to avoid a scenario by which all negotiations with Retail Pharmacy and

Wholesaler Defendants come to halt until April 1.

Thank you for your courtesies and consideration.

Respectfully,

Adam M. Slater